

38/750, 715



UNITED STATES DEPARTMENT OF COMMERCE

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EXAMINER

NOLAND, T

ART UNIT
2856

PAPER NUMBER

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DATE MAILED: 10/26/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

The letter requesting a new office action filed Sept. 2, 1998 has been noted. Note a corrected action was mailed Sept. 1, 1998 so no further office action is needed. Applicant's next response is due Dec. 1, 1998. However the examiner has been notified that no additional extension fee will be charged since the original response was not held nonresponsive until the corrected action.

~~REAGB~~ The possible error
is regretted. 10/19/98

THOMAS P. NOLAND
PRIMARY EXAMINER
GROUP 2200

Thomas Noland

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1. The preliminary amendment filed March 19, 1997 has been entered.
2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
3. Appropriate ones and forms of the headings listed in paragraph 4 below must be inserted into the application, preferably by Applicant.
4. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

- (a) Title of the Invention.
- (b) Cross-References to Related Applications (if any).
- © Statement as to rights to inventions made under Federally-sponsored research and development (if any).
- (d) Background of the invention.
 1. Field of the Invention.
 2. Description of the Related Art including information disclosed under 37 CFR 1.97-1.99.
- (e) Summary of the Invention.
- (f) Brief Description of the Drawing.
- (g) Description of the Preferred Embodiment(s).
- (h) Claim(s).
- (I) Abstract of the Disclosure.

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5. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are replete with indefinite language, bordering on incomprehensibility as to the limits as to what is being claimed. The following particular unclarities are noted:

Vague terms and/or improper alternative claiming: Claim 1, lines 2-3 "such asand/or cells" and line 10 "in particular"; claim 4, lines 3-7 "at least.... pressure impulse"; claim 6, lines 4-6 "for electrophoresis.... neutral molecules"; claim 7, lines 3-7 "at least.... reactor compartment"; claim 8 in its entirety; claim 9, lines 3-4 "the number stepping motor; claim 12 in its entirety; claim 14, line 8; claim 16, lines 3-7 "such as..... complex formation"; claim 17, lines 6-13 "optionally as.... serum 2"; claim 18, lines 3-4", e.g. labelled.... different organisms,"; claim 19, lines 3-6 "immediately by G derivatives"; claim 20 in its entirety; claim 22, lines 3-7 "by confocal... object plane"; claim 24, line 8 "continuously or discontinuously in time"; claim 26, lines 2-9 "for the... withdrawal device"; claim 27, in its entirety; claim 29, lines 2-5 "for the... derived therefrom"; and claim 31, lines 4-5 "inner or... viral envelope". For clarity in claim 1, line 9 after "withdrawn" a comma should be inserted. There is no antecedent for "said other" in claim 2, line 2. The meaning of "performed independently in terms of a gathering process" in claim 3, lines 4-5 is unclear. In claim 5, in line 2 a comma should be inserted after "capillary" and in line 4, a comma should be inserted after "tip". In claim 6; in line 8, "the solution on the" should be --- solution on a ---; in line 9, "the other" should be --- an opposing ---; in line 10 "the

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solution on the side of the" should be --- solution on a side of a ---; in line 11 "and the" should be --- and --- and in line 12 "the" should be --- a ---. There is no proper link to prior and antecedent by "The two compartments" in claim 6, lines 11-12. In claim 7; in line 4, "the pressure in the" should be --- pressure in a --- and in line 5 "the receptor" should be --- a receptor ---- and "to the" should be --- to ----. In claim 8, line 3 "the filling" should be ---- , a filling ---. The remaining claims should upon amendment be reviewed for additional unclarities especially lack of proper antecedent or acknowledgment of prior antecedent. Claim 26 is additional unclear because it does not claim all the components necessary to carry out the process of claim 20.¹⁹
²⁰ Similarly claims 28-32 are unclear because they do not include the necessary steps to carry out the claimed uses.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 28-32 each provides for the use of the withdrawal method of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 28-32, each, is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

8. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not understood from page 6, lines 7-14 or elsewhere in the disclosure how space and time of the withdrawal are determined by analytical signal which is correlated with the small component to be withdrawn. Exactly from what signal and how this is done does not appear to be readily apparent to one of ordinary skill. It is unclear if applicant is relying on

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PCT/EPA4/001.P for this or some other portion of the analysis. If some other portion, which portion? It is noted such a non U.S. Patent document cannot be relied upon since this material appears to be claimed and thus is considered to be essential material.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 26 and 28-32 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Eigen et al., Ref. AT cited by Applicant.

Note especially the abstract, the first two text paragraphs on page 5740 and page 5741.

13. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. Ref. AC, Ashkin et al., Ref. AS, North, Jr., Ref. AD, Gohde et al., Ref.AA, or Weber et al., Ref. AR, all cited by Applicant. Martin et al. in its abstract, col. 3, lines 7-25; col. 4, lines 5-63; col. 5, lines 7-25; col. 4, lines 5-63; col. 5, line 59 - col. 6, line 8, and col. 6, lines 22-41 shows an extraction system operated substantially as claimed, as best understood, for which if not inherently having an extraction volume in the claimed range it would have been obvious to use such a range given the material being analyzed. Extraction of a component by a second laser beam as set forth

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in the abstract in combination with a video system 42 and computer may be considered to be an optical or analysis system as claimed. Information on time and place of extraction appears to be disclosed on col. 6, lines 34-41. Ashkin et al. similarly makes a withdrawal method as claimed obvious in view of its disclosure especially page 769 left hand column and page 770 column 1,
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paragraph 5 column 2, paragraph 1. Note mention is made of laser trapping in the first paragraph. The exact time and place of the withdrawal would have been readily available to one of ordinary skill from the video signal. The microscope or video system could be considered an optical analysis system. The use of the laser trapping process would if not inherently creating volume elements in the claimed range be obvious to use in such small ranges as deducible from the bottom of the first column. North, Jr. similarly makes a withdrawal method like that of claim 1 obvious, if not inherent, from its teachings in Figs. 5 and 6 and col. 10, line 49 - col. 11, line 10 and col. 11, lines 42-45. Note tube 93 is controlled by driver circuitry 98 and is moved in a manner to extract selected cells. The driver signal would obviously contain information on the time and place of extraction. A fluorescence meter is used as an optical analysis system. From the dimensions of the tube opening 94 set forth in col. 10, lines 55-67 it is obvious that extracted volume elements lie in the claimed range. Gohde et al. especially in Figs. 5 and 7 and col. 6, line 49 - col. 7, line 52 shows or makes obvious a system like that of claim 1 for reasons analogous to those given for North, Jr. to which it is very similar. Weber et al. especially in Fig. 2 on page 8 discloses a withdrawal system for the extraction of cells and using video and computer equipment, i.e. an optical analysis system and providing information about the time and place of

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extraction. It would have been obvious, even if not inherent, to have the extraction volume
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elements ~~i.e.~~ in the claimed range because of the use of the laser. With regard to claims 2-32 these claims apparently include, to the best they are understood, no additional features or elements not inherent or obvious from the teachings making claim 1 obvious from the above references since they appear to claim features obvious to use in, or with, such systems.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rigler et al., possibly not prior art to applicant, is the abstract of a PCT publication cited by Applicant and in the IPER. The other references show systems for collecting small sample volumes and/or optical analysis.

15. Status inquiries should be directed to the group receptionist at (703) 305-4900.

Any inquiry concerning this communication should be directed to Tom Noland at telephone number (703) 305-4765.

Noland:lsd

January 28, 1998

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